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| 10/612,754 | 07/01/2003 | Thomas W. Mower | 14564.37.1 | 5557 |

7590 04/06/2007
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| ART UNIT | PAPER NUMBER |
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1615

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/612,754 | Applicant(s) MOWER ET AL. | |
| | Examiner Humera N. Sheikh | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 13-19, 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 20 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Receipt of the Response and Amendment after Non-Final Office Action and Applicants Arguments/Remarks, both filed 01/11/07 is acknowledged.

Claims 1-23 are pending in this action. Claims 1, 13, 18, 20 and 23 have been amended. Claims 13-19, 21 & 22 have previously been withdrawn. Claims 1-12, 20 and 23 stand rejected.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-12, 20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Su *et al.* (U.S. Patent Publication No. 2002/0068102 A1) in view of Fischer *et al.* (U.S. Patent No. 5,433,965) OR Downton *et al.* (U.S. Patent No. 5,411,755).

The instant invention is drawn to a dietary supplement comprising: noni fruit; Luo Han Guo in an effective amount to mask flavor and/or scent of the noni fruit; and water.

The instant invention is also drawn to a method of improving the taste and odor of noni-based dietary supplements, comprising: providing a noni fruit product; and mixing with the noni fruit product Luo Han Guo in an effective amount to mask flavor and/or scent of the noni fruit; the Luo Han Guo including: powdered Luo Han Guo; and liquid Luo Han Guo; whereby the

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powdered Luo Han Guo provides a masking effect to cover the unpleasant tastes and/or odors of the noni and the liquid Luo Han Guo acts as a sweetener for the dietary supplement.

The instant invention is also drawn to a method of improving the taste and odor of a noni-based dietary supplement, while simultaneously prolonging the shelf life thereof, comprising: providing a noni-based fruit product; mixing with the noni fruit product: Luo Han Guo in an effective amount to mask flavor and/or scent of the noni fruit; the Luo Han Guo including powdered Luo Han Guo; liquid Luo Han Guo; raspberry fruit concentrate; and blueberry fruit concentrate.

Su et al. ('102) teach a dietary supplement to reduce cellular damage within the human body, whereby the dietary supplement includes reconstituted *Morinda citrifolia* (noni) fruit juice. The dietary supplement may also include other natural juices, such as natural blueberry juice concentrate and/or another natural juice concentrate. In one implementation, where liquid is extracted from the fruit of *Morinda citrifolia* to create the dietary supplement, it is referred to as 'Tahitian Noni' (see Abstract); (page 1, ¶ 13); (pg. 3, ¶ 28).

Su et al. teach that when the *Morinda citrifolia* fruit is ripe or overripe, the fruit provides a foul odor and/or taste (pg. 2, ¶ 25).

To prepare the supplement, *Morinda citrifolia* juice and puree are typically blended in a homogeneous blend, after which they are mixed with other ingredients, such as flavorings, sweeteners, nutritional ingredients, botanicals, extracts, and/or colorings. For example, flavorings may include artificial and/or natural flavor or ingredients that contribute to palatability. Sweeteners taught include natural sugars, artificial and high-intensity sweeteners.

Specific sweeteners taught include natural sugars derived from corn, sucralose, stevia, saccharin, etc. (pg. 3, ¶ 35).

Consumption amounts of the dietary supplement may include more than one ounce per day or less than one ounce per day (pg. 1, ¶ 15 – pg. 2 ¶ 15).

With regard to the instant ‘method of improving taste and odor’ of noni based dietary supplements, it is the position of the Examiner that the instant method would be considered *prima facie* obvious based on the disclosure and teachings of Su *et al.*, as Su *et al.* teach a noni-based (*Morinda citrifolia*) dietary supplement that comprises at least one of flavorings and sweeteners (see for instance, Claim 13).

While Su *et al.* do not explicitly teach the instant amounts of noni fruit, the Examiner points out that, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It is the Examiner’s position that Applicants have not demonstrated any surprising or unexpected results that accrue from the claimed amounts of noni fruit. The prior art clearly recognizes and teaches formulations based on noni fruit, particularly, *Morinda citrifolia*, used in dietary supplement formulations.

Su *et al.* as discussed above, teach that *Morinda citrifolia* provides a foul odor and/or taste when ripe or overripe. Su *et al.* also teach that flavoring agents, sweetening agents and the like are added in the supplement to contribute to palatability.

Su *et al.* do not teach inclusion of Luo Han Guo and raspberry concentrate.

Fischer *et al.* ('965) teach beverage and sweetening compositions comprising Luo Han Guo. The Luo Han Guo is provided in serum, puree or juice form and is used as a sweetening ingredient in place of sugar (see reference column 1, line 25 – col. 2, line 46). The use of Luo Han Guo allows for good tasting, storage-stable beverages and can be used in beverages, such as fruit juices and fruit juice-containing beverages (col. 2, lines 29-35). Luo Han Guo provides for a reduced calorie, flavoring system that has acceptable mouth feel and taste characteristics, particularly, a beverage without off-flavors (col. 2, lines 47-62); (col. 12, lines 27-30).

The Luo Han Guo-containing sweet juices can be concentrated but are mostly used as a single strength juice or as a dry powder (col. 4, lines 20-40).

Luo Han Guo is preferably present at an amount of from 0.25 to 10% (col. 10, lines 27-36). See also Examples on cols. 16-19. This amount is an overlapping amount, which reads on the instantly claimed amount of from about 0.1% to about 3%.

Flavoring agents that can be used include raspberry, blueberry and the like (col. 4, lines 4-19); (col. 11, lines 44-59). The flavoring agents are provided in amounts of from 0.01% to 3% by weight (col. 11, lines 26-32).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the Luo Han Guo and raspberry flavorants as taught by Fischer *et al.* within the dietary supplement of Su *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Fischer *et al.* teach a high-intensity sweetener, Luo Han Guo and teach that it is used as a sweetening agent, useful for providing good taste, with acceptable mouth feel and taste characteristics and also teach that

additional flavorants and juices include raspberry to make low calorie beverages. The expected result would be an improved, palatable, reduced-calorie dietary supplement formulation.

With regard to the instantly claimed extraction amounts of Luo Han Guo and/or ORAC values, it is the position of the Examiner that it is deemed obvious to one of ordinary skill in the art to determine suitable or effective amounts and/or values through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters attainable within the art. Absent a showing of unexpected results that accrue from the instant amounts/values, the instant amounts/values would be determined by the normal optimization process by the skilled artisan.

The teachings of Su *et al.* are discussed above. Su *et al.* teach that Morinda citrifolia provides a foul odor and/or taste when ripe or overripe. Su *et al.* also teach that flavoring agents, sweetening agents and the like are added in the supplement to contribute to palatability.

Su *et al.* do not teach inclusion of Luo Han Guo and raspberry concentrate.

Downton *et al.* ('755) teach a sweet juice composition comprising Luo Han Guo. The sweet fruit juice and concentrate can be made from Luo Han Guo juice so that it does not contain objectionable off-flavors and does not reform substantial quantities of off-flavors during storage (see reference column 2, lines 1-26); (col. 3, lines 3-15) and Examples at cols. 12-15. An objective is to also produce a fruit juice, which is lower in sugar and calories by blending the very sweet (Luo Han Guo) juice with other fruit juices (col. 2, lines 27-30). Other suitable fruit

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juices disclosed include raspberry fruit juices (col. 10, lines 30-50). The sweet juice has a pH of less than about 4.5 (claim 18).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the Luo Han Guo and raspberry juices as taught by Downton *et al.* within the dietary supplement of Su *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Downton *et al.* teach a natural sweetener, Luo Han Guo, whereby the sweet fruit juice and concentrate can be made from Luo Han Guo juice so that it does not contain objectionable off-flavors and does not reform substantial quantities of off-flavors during storage and also teach that additional fruit juices, such as raspberry are included in the Luo Han Guo juice to make low calorie (lower sugar) beverages. The expected result would be an enhanced, palatable, low-calorie dietary supplement formulation.

With regard to the instantly claimed extraction amounts of Luo Han Guo and/or ORAC values, it is the position of the Examiner that it is deemed obvious to one of ordinary skill in the art to determine suitable or effective amounts and/or values through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters attainable within the art. Absent a showing of unexpected results that accrue from the instant amounts/values, the instant amounts/values would be determined by the normal optimization process by the skilled artisan.

Claims 1-12, 20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yegorova (U.S. Patent No. 6,387,370 B1) in view of Fischer *et al.* (U.S. Patent No. 5,433,965) OR Downton *et al.* (U.S. Patent No. 5,411,755).

The instant invention is drawn to a dietary supplement comprising: noni fruit; Luo Han Guo in an effective amount to mask flavor and/or scent of the noni fruit; and water.

The instant invention is also drawn to a method of improving the taste and odor of noni-based dietary supplements, comprising: providing a noni fruit product; and mixing with the noni fruit product Luo Han Guo in an effective amount to mask flavor and/or scent of the noni fruit; the Luo Han Guo including: powdered Luo Han Guo; and liquid Luo Han Guo; whereby the powdered Luo Han Guo provides a masking effect to cover the unpleasant tastes and/or odors of the noni and the liquid Luo Han Guo acts as a sweetener for the dietary supplement.

The instant invention is also drawn to a method of improving the taste and odor of a noni-based dietary supplement, while simultaneously prolonging the shelf life thereof, comprising: providing a noni-based fruit product; mixing with the noni fruit product: Luo Han Guo in an effective amount to mask flavor and/or scent of the noni fruit; the Luo Han Guo including powdered Luo Han Guo; liquid Luo Han Guo; raspberry fruit concentrate; and blueberry fruit concentrate.

Yegorova ('370) teaches dietary supplement compositions that include extracts of *Morinda citrifolia*, also called Noni juice, and blueberry extracts (see Abstract); (col. 5, lines 22-26); (col. 6, line 66 – col. 7, line 10).

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The preparations may be in solid form, such as a capsule, powder or granule, or a tablet form. Alternatively, the compositions may be dispersed into a suitable liquid. The composition may also be administered orally, preferably two to three times daily (col. 5, lines 14-20); (col. 11, lines 46-56).

The composition may comprise *Morinda citrifolia* extract in an amount ranging from about 50 mg to about 150 mg and blueberry extract in an amount ranging from about 25 mg to about 75 mg (col. 4, lines 21-34); (col. 7, lines 35-42); (col. 8, lines 62-66).

In a preferred embodiment, the compositions may comprise 100 mg of *Morinda citrifolia* extract obtained by extracting the *Morinda citrifolia* fruit with water (col. 8, lines 1-7).

According to Yegorova, compositions comprising blueberry extract have been used to retard the aging process, as blueberries comprise large amounts of antioxidants. Blueberries rank in the top five of an antioxidant assay called ORAC (oxygen radical absorbance capacity) (col. 7, lines 7-10); (col. 8, lines 31-66).

Example 1 at columns 12-13 demonstrates a composition that includes *Morinda citrifolia* (100 mg) and blueberry extract (50 mg).

While Yegorova does not explicitly teach the instantly claimed amounts of noni fruit, the Examiner points out that, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It is the Examiner’s position that Applicants have not demonstrated any surprising or unexpected results

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that accrue from the claimed amounts of noni fruit. The prior art clearly recognizes and teaches dietary formulations based on noni fruit, particularly, *Morinda citrifolia* in combination with antioxidant-containing blueberry extract.

Yegorova does not teach inclusion of Luo Han Guo and raspberry concentrate.

Fischer *et al.* ('965) teach beverage and sweetening compositions comprising Luo Han Guo. The Luo Han Guo is provided in serum, puree or juice form and is used as a sweetening ingredient in place of sugar (see reference column 1, line 25 – col. 2, line 46). The use of Luo Han Guo allows for good tasting, storage-stable beverages and can be used in beverages, such as fruit juices and fruit juice-containing beverages (col. 2, lines 29-35). Luo Han Guo provides for a reduced calorie, flavoring system that has acceptable mouth feel and taste characteristics, particularly, a beverage without off-flavors (col. 2, lines 47-62); (col. 12, lines 27-30).

The Luo Han Guo-containing sweet juices can be concentrated but are mostly used as a single strength juice or as a dry powder (col. 4, lines 20-40).

Luo Han Guo is preferably present at an amount of from 0.25 to 10% (col. 10, lines 27-36). See also Examples on cols. 16-19. This amount is an overlapping amount, which reads on the instantly claimed amount of from about 0.1% to about 3%.

Flavoring agents that can be used include raspberry, blueberry and the like (col. 4, lines 4-19); (col. 11, lines 44-59). The flavoring agents are provided in amounts of from 0.01% to 3% by weight (col. 11, lines 26-32).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the Luo Han Guo and raspberry flavorants as taught by

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Fischer *et al.* within the dietary supplement of Yegorova. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Fischer *et al.* teach a high-intensity sweetener, Luo Han Guo and teach that it is used as a sweetening agent, useful for providing good taste, with acceptable mouth feel and taste characteristics and also teach that additional flavorants and juices include raspberry to make low calorie beverages. The expected result would be an improved, palatable, reduced-calorie dietary supplement formulation.

With regard to the instantly claimed extraction amounts of Luo Han Guo and/or ORAC values, it is the position of the Examiner that it is deemed obvious to one of ordinary skill in the art to determine suitable or effective amounts and/or values through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters attainable within the art. Absent a showing of unexpected results that accrue from the instant amounts/values, the instant amounts/values would be determined by the normal optimization process by the skilled artisan.

The teachings of Yegorova are delineated above.

Yegorova do not teach Luo Han Guo and raspberry concentrate.

Downton *et al.* ('755) teach a sweet juice composition comprising Luo Han Guo. The sweet fruit juice and concentrate can be made from Luo Han Guo juice so that it does not contain objectionable off-flavors and does not reform substantial quantities of off-flavors during storage (see reference column 2, lines 1-26); (col. 3, lines 3-15) and Examples at cols. 12-15. An objective is to also produce a fruit juice, which is lower in sugar and calories by blending the

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very sweet (Luo Han Guo) juice with other fruit juices (col. 2, lines 27-30). Other suitable fruit juices disclosed include raspberry fruit juices (col. 10, lines 30-50). The sweet juice has a pH of less than about 4.5 (claim 18).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the Luo Han Guo and raspberry juices as taught by Downton *et al.* within the dietary supplement of Yegorova. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Downton *et al.* teach a natural sweetener, Luo Han Guo, whereby the sweet fruit juice and concentrate can be made from Luo Han Guo juice so that it does not contain objectionable off-flavors and does not reform substantial quantities of off-flavors during storage and also teach that additional fruit juices, such as raspberry are included in the Luo Han Guo juice to make low calorie (lower sugar) beverages. The expected result would be an low-calorie dietary supplement composition that offers improved taste and flavoring.

With regard to the instantly claimed extraction amounts of Luo Han Guo and/or ORAC values, it is the position of the Examiner that it is deemed obvious to one of ordinary skill in the art to determine suitable or effective amounts and/or values through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters attainable within the art. Absent a showing of unexpected results that accrue from the instant amounts/values, the instant amounts/values would be determined by the normal optimization process by the skilled artisan.

Pertinent Art

Prior art not relied upon but deemed relevant by Examiner:

- Xiong *et al.* (U.S. Patent No. 6,299,925 B1)

Xiong *et al.* teach a green tea extract formulation comprising Noni fruit, obtained from *Morinda citrifolia* plant. The formulation also contains fruit extracts, such as blueberry and raspberry extract (see Abstract; col. 6, lines 61-65; col. 8, Example VII; and Claim 23).

Response to Arguments

Applicant's arguments filed 01/11/07 have been fully considered but they are not persuasive.

35 U.S.C. §103(a) Rejections of claims 1-12, 20 and 23 over Su *et al.* (U.S. Patent Publication No. 2002/0068102 A1) in view of Fischer *et al.* (U.S. Patent No. 5,433,965) OR Downton *et al.* (U.S. Patent No. 5,411,755).

Applicant argued, "Su is completely devoid of teaching or suggesting a dietary supplement that includes, "noni fruit, Luo Han Guo in an effective amount to mask flavor and/or scent of the noni fruit, and water. Su is completely devoid of teaching or suggesting a method of improving the taste and odor of the noni fruit dietary supplement. In part, this is because Su is completely devoid' of teaching or suggesting, that the products-obtained from the noni fruit utilized in the dietary supplement or that the dietary supplement itself has a bad order or taste that needs to be masked."

Applicant's arguments have been considered but were not found persuasive. Su, as discussed above, teach a dietary supplement to reduce cellular damage within the human body, whereby the dietary supplement includes reconstituted *Morinda citrifolia* (noni) fruit juice. The

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dietary supplement may also include other natural juices, such as natural blueberry juice concentrate and/or another natural juice concentrate. Admittedly, while Su does not teach the inclusion of Luo Han Guo, the secondary references of Fischer or Downton remedy this deficiency of Su by their respective teachings of incorporating Luo Han Guo, which is useful as a sweetening ingredient in place of sugar (see col. 1, line 25 – col. 2, line 46 of Fischer). Fischer also teach that the use of Luo Han Guo allows for good tasting, storage-stable beverages and can be used in beverages, such as fruit juices and fruit juice-containing beverages (col. 2, lines 29-35). The Fischer reference clearly teaches the beneficial effects that accrue from the use of Luo Han Guo, namely, sweetening effects. Downton also teaches sweet juices comprising Luo Han Guo, whereby the juices do not contain objectionable off-flavors. Applicant's argument that 'Su is devoid in the teaching that products obtained from the noni-fruit itself has a bad odor or taste' was not persuasive since the reference vividly teaches the use of noni-fruit; and whether or not Su suggests that noni-fruit itself has a bad odor is irrelevant, since a product and its' properties are inseparable. In this instance, Su expressly teaches inclusion of noni-fruit, employed in dietary supplement formulations. The argument that "Su do not teach Luo Han Guo in an effective amount to mask flavor and/or scent of the noni fruit" was not persuasive since the limitation 'an effective amount' is fairly relative in scope and does not set forth any upper or lower limits of Luo Han Guo. Moreover, the secondary references (Fischer) teach Luo Han Guo preferably present at an amount of from 0.25 to 10% (see col. 10, lines 27-36); and (Examples on cols. 16-19), which reads on the instantly claimed amount of from about 0.1% to about 3% and thus would be considered to be "an effective amount" that masks flavor and/or scent as instantly recited.

Applicant argued, “The Office fails to acknowledge that ‘Luo Han Guo is seldom used as fresh juice due to the problems of storing it, its unattractive vegetable flavor and its tendency to form off-flavors’. The Office fails to acknowledge that the sweet juice compositions are produced by ‘mixing the sweet juice with a sugar component’ and has ‘about 40% to about 60% sugars, such as glucose, fructose, and sucrose. Fischer is also completely devoid of teaching or suggesting a dietary supplement that includes, “noni fruit, Luo Han Guo in an effective amount to mask flavor and/or scent of the noni fruit, and water.”

These arguments were not persuasive. The argument that the ‘Office fails to acknowledged problems demonstrated by Luo Han Guo’ was not persuasive since the reference teachings, as a whole are considered, whereby the benefits imparted by Luo Han Guo, as taught by Fischer outweigh the negative attributes due to the use of Luo Han Guo. The argument that Fischer includes sugars (i.e., glucose, fructose, etc.) was not persuasive since Applicants themselves desire the use of sugars or sweetening agents (see for instance, instant claim 11, which claims nectar, sucralose, corn syrup, etc.). Applicant’s argument that “Fischer do not teach Luo Han Guo in an effective amount to mask flavor and/or scent of the noni fruit” was not persuasive since the limitation does not define the minimum and maximum levels of Luo Han Guo required. Additionally, it is noted that Fischer teach effective amounts (from 0.25 to 10%), which meets the claimed amounts of from about 0.1% to about 3% and thus would be effective amounts, fully capable of masking flavor and/or scent.

Applicant argued, “The Office fails to acknowledge that ‘Luo Han Guo is seldom used fresh due to the problems of storing it, its unattractive vegetable flavor and its tendency to form off-flavors’. Also, Downton is also completely devoid of teaching or suggesting a dietary supplement that includes, “noni fruit, Luo Han Guo in an effective amount to mask flavor and/or scent of the noni fruit, and water.”

These arguments were not persuasive since preferred as well as non-preferred teachings are considered in a prior art reference. The reference, while disclosing unfavorable attributes of

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Luo Han Guo also suggests its' favorable sweetening effects in a juice composition. The argument that 'Luo Han Guo is not taught in an effective amount to mask flavor and/or scent' was not persuasive, since the prior art clearly teaches compositions employing the same ingredient, Luo Han Guo, used for the same purpose (sweetening properties) and field of endeavor as that desired by Applicants. The limitation does not impart a *patentable* distinction over the explicit reference teachings.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, while the primary Su reference does not disclose the addition of Luo Han Guo, the secondary references (Fischer & Downton) resolve this deficiency of the primary

reference by their explicit teachings of the use and benefits of Luo Han Guo in dietary supplement compositions.

35 U.S.C. §103(a) Rejections of claims 1-12, 20 and 23 over Yegrova *et al.* (USPN 6,387,370) in view of Fischer *et al.* (U.S. Patent No. 5,433,965) OR Downton *et al.* (U.S. Patent No. 5,411,755).

Applicant argued, “The Office Action alleges that Yegorova teaches a composition that includes extracts of noni juice and blueberry extracts. However, the Office fails to acknowledge that this citation also teaches that the composition further includes ‘red wine extract, prune extract, blueberry extract, pomegranate extract, apple extract and an enzyme mixture. Yegorova is completely devoid of teaching or suggesting a dietary supplement that includes, “noni fruit, Luo Han Guo in an effective amount to mask flavor and/or scent of the noni fruit, and water.”

Applicant’s arguments have been considered but were not found persuasive. The argument that Yegorova teaches a composition that includes further extracts (i.e., red wine, prune, apple, etc.) was not persuasive since it is noted that the instant claims utilize “comprising” claim language, thus permitting the presence of additional ingredients besides from those instantly recited, which would include the red wine extract, prune extract, blueberry extract, etc. disclosed by Yegorova. The argument that Yegorova does not teach Luo Han Guo in an effective amount to mask flavor and/or scent’ was not persuasive since this limitation is fairly generic and does not set forth any upper or lower limits of Luo Han Guo agent. Moreover, the Examiner points out that, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to

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discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

In response to applicant's argument that there is no suggestion to combine the references - namely, Yegorova, Fischer and Downton, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, while the primary Yegorova reference does not disclose the addition of Luo Han Guo, the secondary references (Fischer & Downton) remedy this deficiency based on their explicit teachings of the use of Luo Han Guo in dietary supplement compositions. The prior art amply recognizes the advantages of incorporating Luo Han Guo in dietary supplement formulations. Moreover, it is not necessary that the prior art teach each and every property associated with a particular ingredient, but merely that the prior art teach the particular component, employed in a similar field of endeavor is sufficient.

It remains the position of the Examiner that the instant claims, as presently recited, remain generic enough to read on the explicit teachings of the prior art of record delineated above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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HUMERA N SHEIKH
PRIMARY EXAMINER

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April 02, 2007

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